IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION

Master File No. 2:12-MD-02327 MDL No. 2327

THIS DOCUMENT RELATES TO ETHICON WAVE 1 CASES

JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE GENERAL OPINIONS OF MICHAEL P. WOODS, M.D.

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, "Defendants") submit this response in opposition to Plaintiffs' motion to exclude the general opinions of Michael P. Woods, M.D. (Doc. 2043) (hereinafter, "Ex. A to Plaintiffs' Motion").

INTRODUCTION

Dr. Woods is an obstetrician and gynecologist focusing on treating incontinence, prolapse, and other pelvic floor disorders. Ex. A to Plaintiffs' Motion, Expert Report at 1. He has been board-certified in obstetrics and gynecology since 1991 and reconstructive surgery since 2013, the first year the certification became available. *Id.* at 1 and Woods Curriculum Vitae (attached to Expert Report). Dr. Woods operated his own private practice in Bellevue, Nebraska from 1997-2013. *Id.*

In the 1990s, the Burch Colposuspension was his primary procedure for genuine stress urinary incontinence. Expert Report at 2; Ex. B, Woods Oct. 5, 2015 Dep. 139:10-140:7. He began using the TVT in 1999 after "monitoring the initial clinical literature, paying close attention to the mesh erosion/exposure rates." Expert Report at 2. He has performed thousands of procedures with TVT mesh. *Id.* at 5. He is also experienced with suburethral slings using

Autologous slings, porcine skin, bovine dura mater, vicryl mesh, Gore-Tex mesh, Mersilen mesh. *Id.* at 2.

Currently, Dr. Woods works as a Urogynecologist for Shenandoah Medical Center in Iowa. *Id.* at 1. A member of the American Urogynecology Society, International Urogynecology Association, and the American Board of Obstetrics and Gynecology, he has presented both nationally and internationally on areas involving gynecology and pelvic floor disorders, including lectures on polypropylene mesh. *Id.*; Ex. B, Woods Oct. 5, 2015 Dep. 87:5-11; 89:4-14.

In these cases, Dr. Woods intends to offer opinions generally addressing the utility and safety of the TVT and TVT-O devices. His opinions are based upon his education, medical training, clinical experience, extensive review of medical literature, position statements, guidelines, practice patterns, curricula, and various other material reflected in his reliance list. Expert Report at 1-5; Ex. C, Reliance List. His is qualified to opine on these topics and, as detailed below, his opinions are supported by reliable methodology.

Plaintiffs have challenged certain aspects of Dr. Woods' opinions, and as set forth below, Plaintiffs' arguments lack merit and should be denied.

ARGUMENT

Ethicon incorporates by reference the standard of review for *Daubert* motions as articulated by the Court in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 701 (S.D. W. Va. 2014).

I. Dr. Woods is qualified to render opinions regarding the utility and safety of the TVT and TVT-O devices, and his opinions are supported by reliable methodology.

Plaintiffs claim that Dr. Woods is not competent to testify that TVT and TVT-O are reasonably safe for their intended use on the basis that he has inadequate expertise with the design process and product development and because he has been unable to locate certain

records that confirm his personal success and complication rates. As set forth below, Dr. Woods does not intend to provide design process opinions, and he is well qualified to testify about the safety and utility of the devices.

A. Ethicon's internal product design process documents are irrelevant to Dr. Woods's safety and utility opinions.

Relying exclusively on this Court's opinion in *Winebarger v. Boston Scientific Corp.*, 2015 WL 1887222 (S.D. W. Va. Apr. 24, 2015), Plaintiffs argue that because Dr. Woods has not reviewed Ethicon's internal documents about its design process, he cannot opine about any issues that touch upon product design. The *Winebarger* opinion, however, does not stand for the proposition asserted, and Plaintiffs have manufactured an issue that is not based in law or logic.

Dr. Woods merely intends to opine about the safety and efficacy of TVT and TVT-O supported by his extensive education, medical training, clinical practice, and very lengthy analysis of the medical literature. Expert Report at 1-5; Ex. B, Woods Oct. 5, 2015 Dep. at 189. He does not, however, intend to offer *any* opinion regarding the adequacy of Ethicon's internal design procedures or Ethicon's compliance with industry standards during the development of the devices. Those were the issues that were addressed in *Winebarger*.

In *Winebarger*, Boston Scientific challenged the opinion of the plaintiff's proposed expert, Dr. Bobby Shull, regarding Boston Scientific's failure to "follow its own internal

¹ As he explained in his deposition:

Q (by defense counsel): The judge's order at page 5 says the parties' primary focus should be the scientific and medical literature suggesting or contesting that the TVT is defectively designed and that it is not reasonably safe \dots Is that something you investigated?

A: Yes. And in doing so, what I wanted to do is look at the highest-level evidence, which would be the randomized controlled studies, the systemic review, the meta-analysis, and cohort studies .

^{. .} but anything below that I felt was lower-level evidence that did not pertain to this. (objection of counsel omitted).

Ex. B, Woods Oct. 5, 2015 Dep. at 189:8-22.

² Dr. Woods did review certain Ethicon internal documents related to the TVT device. As he explained: "I have reviewed the internal documents; however, I've not allowed anecdotal, non-evidence-based information to affect the safety and efficacy that I was asked to review." Ex. B, Woods Oct. 5, 2015 Dep. at 14:14-23.

protocols" and its "lack of due diligence in the design and development" of the product in issue. Winebarger, at *14. Dr. Shull, however, did not review any documents related to Boston Scientific's standard operating procedures or its design protocols. *Id.* Consequently, this Court held that "[w]ithout any reliable, demonstrated knowledge of BSC's internal design procedures, Dr. Shull cannot substantiate his opinion that these procedures were (1) departures for the norm; (2) not followed by BSC; or (3) lacking in any way." *Id.*

In contrast to Dr. Shull in *Winebarger*, Dr. Woods does not intend to offer *any* opinions regarding Ethicon's "internal design procedures," and therefore, it was unnecessary for Dr. Woods to review any of Ethicon's internal documents related to design procedures. In fact, in *Winebarger*, the Court allowed Dr. Patrick Culligan, a defense expert urogynecologist, to opine about the safety and efficacy of the medical device, even though the Court concluded that Dr. Culligan was not competent to testify about mesh design. *Id.* at *33-35. Plaintiffs have chosen to focus on an opinion Dr. Woods has not offered related to documents Dr. Woods was not even asked to review. Quite simply, Plaintiffs have not shown and cannot show that a review of Ethicon's internal product design process documents was necessary for any of the opinions that Dr. Woods intends to provide in these cases.

B. The complication and satisfaction rates identified by Dr. Woods are consistent with the rates reported in peer-reviewed medical literature.

Plaintiffs also argue that Dr. Woods should be precluded from testifying about the safety and efficacy of TVT and TVT-O because he relies "in part" on his personal experiences for which he has not been able to come forward with records to corroborate. Doc. 2043, p. 8. Dr. Woods's patients complication rates would have been in his patients' medical records and billing records, but his billing records are no longer available. Ex. B, Woods Oct. 5, 2015 Dep. at 146:12-147:20; 220:15-17.

This Court has specifically rejected Plaintiffs' same argument in this MDL litigation:

The plaintiff takes issue with Dr. Robboy's reliance on his clinical experience because she has no way of "independently verifying" opinions. The plaintiffs argument has no practical merit. Numerous expert witnesses throughout the course of these MDLs have relied on their clinical experience in forming their expert opinions. Such practice can hardly be described as a "mystery." If *Daubert* required an expert witness to independently verify every single clinical experience he had over the course of his career, the court would never make it past pre-trial motions.

Ex. D, *Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, Doc. 265, p. 40 (S.D. W. Va. Nov. 20, 2014); *see also Winebarger*, 2015 WL 1887222, at *34 (finding that expert's inability to provide "exact statistics" about the outcome of his patients did not render his personal experience opinions unreliable and that "such detail is not required under *Daubert* to opine as to '*large-scale* safety and efficacy of the Uphold device'"); *Trevino v. Boston Scientific Corp.*, 2016 WL 1718836, at *33 (S.D. W. Va. Apr. 28, 2016) (same). For these same reasons, the Court should reject Plaintiffs' argument here.

In any event, Dr. Woods's extensive personal experiences, coupled with his reliance on the medical literature, make him well qualified to opine about the safety and utility of the devices. Dr. Woods is a skilled urogynecologist with over twenty years of experience treating female pelvic floor disorders, as well as the complications resulting from the implantation of transvaginal mesh. Expert Report at 1-2. He has implanted over a thousand TVT and TVT-O devices and regularly treats patients for complications related to pelvic surgery. Ex. B, Woods Oct. 5, 2015 Dep. at 11:16-19; 142:18-143:1; 145:19-24. He has participated as a primary investigator in a study of the TVT Secur, which reported positive findings. *Id.* at 46:22-47:22. He also has acted as investigator for studies of Colopast's Altis single incision sling, and on a separate study for a vessel-sealing device for hysterectomy. *Id.* at 62:22-63:5. Further, he has

taught histology in medical school and reviewed pathology slides with pathologists. *Id.* at 90:20-23; 91:16-23.

As reflected in his report, and supported by published studies, the rate of mesh exposure for TVT ranges on average from 1-3% in the peer reviewed literature. Expert Report at 4; id. at 31 (Table 16 Ward/Hilton Trial showing erosion in 1 participant; Cody 2003 Systemic Review demonstrating 1.1% tape erosion rate, 1.4% reoperation for incontinence rate); id. at 34 (Tamussino (2001) showing 2.4% reoperation rate); id. at 33 Table 17 (reflecting various studies and reported rates of complications). Dr. Woods has estimated his exposure rate of 1% and reoperation rate of 3% to be consistent with the published rates, and he has estimated his success rate to be 95-96%. Id. at 4; Ex. B, Woods Oct. 5, 2015 Dep. at 141:8-12. He has found this generally consistent with scientific literature reflecting rates in the upper 80s to low 90s. Id. at 141:14-20; Expert Report at 30 (noting Debodinance (2002) published 87% objective cure rate and 95% satisfaction rate); id. at 34 (citing Schraffordt (2006) demonstrating 24 month objective cure rates from 87.5% to 96%; Nilsson (2012) reporting 89% of patients very satisfied or satisfied; Svenningsen (2013) reporting objective cure rates of 89.9%); id. at 35 (citing Liapis (2010) reporting TVT-O results of 82% cured and 7% improved at 4-year follow-up); id. at 35-36 (citing Angioli (2010) reporting TVT-O results of 73% cure rate and 78.4% would undergo procedure again at 5-year follow-up); id. at 36 (citing Cheng (2012) reporting 92% objective and 90% subjective cure rate at 5-year follow-up; Serati (2013) reporting 90.8% objective and 90.3% subjective cure rate at 5-year follow-up; Lauri Kainen (2011) reporting 86.2% objective cure rate and noting 88.6% would recommend procedure at 5-year follow-up; Athanosiou (2014) reporting

90.3% objective and subjective cure rate in the TVT-0 group at 7.5 year follow-up);³ see also Expert Report at 40 (citing additional studies).

Dr. Woods has applied a sound methodology in formulating his opinions regarding the safety and utility of TVT and TVT-O, and the rates referenced in his report are supported by his thorough review of peer-reviewed publications demonstrating the long term safety of the devices, as well as the repeated endorsements of medical societies. Expert Report at 19-85. His opinions are also supported by his decades of clinical experience and medical training. Although Dr. Woods could not identify documents verifying precise percentages for specific types of complications realized in his practice, that failure does not impact his ability to testify about the safety and efficacy of TVT and TVT-O, as demonstrated by the scientific literature that he has reviewed.

This Court has recognized that a physician may testify that complication rates found in literature are verified by his personal experience. *See, e.g., Tyree v. Boston Scientific Corp,* 54 F. Supp. 3d 501, 585 (S.D. W. Va. 2014) (expert applied reliable methodology supporting opinion that product was safe and effective where opinion was based upon "minimal complications in his clinical practice" which was "on par with the findings of [the] studies' he cites throughout his expert report"); *Carlson v. Boston Scientific Corp.*, 2015 WL 1931311, at *12, *36 (S.D. W. Va. Apr. 28, 2015) (finding Dr. Galloway's method of considering scientific articles and drawing on his clinical experience to reach his opinion regarding degradation to be methodologically sound and allowing Dr. Culligan "by way of his experience with the Uphold device and his review of the relevant scientific literature" to opine how these procedures compare). That is precisely what Dr. Woods will do in these cases. Any alleged inconsistencies or weaknesses in Dr. Woods' testimony go to its weight, not its admissibility. *See Daubert*, 509 U.S. at 596 ("Vigorous cross-

³ Copies of these publications may be provided upon request.

examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence").

C. Dr. Woods's experience with product development is irrelevant to his competence to testify about polypropylene mesh safety and efficacy.

Similar to their attack of Dr. Woods's failure to review Ethicon's design history file, Plaintiffs also suggest that Dr. Woods may not provide safety and efficacy opinions because of his alleged limited involvement in product development. Doc. 2043, pp. 10-12. Yet, Dr. Woods does not intend to offer opinions about Ethicon's process for developing a new product, let alone TVT or TVT-O in particular.

Plaintiffs further suggest that because "product development is a major component of [a] product design" claim, Dr. Woods's opinion regarding TVT safety is somehow deficient for lack of such opinion. *Id.* at 10. Plaintiffs' argument confuses a plaintiff's burden of establishing each element of her product design claim with the duty of a proffered expert. Dr. Woods is under no obligation to address each element of Plaintiffs' design claim, and it is not necessary that he demonstrate expertise in "how a company goes about designing a medical device" or the regulations that apply to that process. *Id.* at 11. Indeed, that is why parties often employ multiple experts. It would be rare in a case such as this for a party to rely upon only one expert to address every element of a plaintiff's claims.

In any event, Dr. Woods has product design experience. For instance, he testified as follows:

Q: Are you an expert in the design of TVT Retropubic and, in particular, for assessing the utility and safety of it for its intended use to treat stress incontinence?

A: Yes. I have taught numerous surgeons the procedure, so on that aspect, I may not be a chemical engineer but, on that, absolutely. Also, in the development of these products, I worked with the engineers as an end user for my input.

Ex. B, Woods Oct. 5, 2015 Dep. at 209:3-13 (objection omitted). He also has worked as a consultant on medical devices that have been patented. *Id.* at 94:17-22.

This Court has found that other physicians with surgical experience were competent to offer opinions similar to that of Dr. Woods. *See, e.g., Tyree*, 54 F. Supp. 3d at 550; *Jones v. Bard, Inc.*, No. 2:11–cv–00114, [Doc. 391], pp. 6–9; *Trevino*, 2016 WL 1718836, at *33. Under Plaintiffs' logic, Plaintiff's own clinician experts, such as Drs. Shull, Rosenzweig, Blaivas, Margolis, and Elliott, would be disqualified from testifying that Ethicon's devices are not safe and effective because they have insufficient product development experience. Plaintiffs' challenge lacks merit.

II. Dr. Woods is qualified to testify regarding the adequacy of warnings.

Dr. Woods has opined on the completeness and accuracy of the TVT and TVT-O IFU warnings from a clinical perspective based on his knowledge of and clinical experience with the risks of the devices. Expert Report at 84-85. Plaintiffs do not challenge, or even address, Dr. Woods's clinical expertise. Instead Plaintiffs argue that he is not qualified to opine on the adequacy of the warnings and IFU because he lacks familiarity with the regulatory process governing the development of such documents.

With respect to Dr. Woods's qualifications, Plaintiffs point out that Dr. Woods has never drafted IFU documents for a medical device, or worked on the development of warnings documents for a medical device or prescription drug. Doc. 2043, p. 12. Plaintiffs quote Dr. Woods's deposition testimony out of context to argue (erroneously) that Dr. Woods has "admitted that he has no expertise in product warnings." *Id.* When read in context, however, it

⁴ During his deposition, Dr. Woods did note that his expertise in this area is strengthened by his service with the ACOG Committee on Professional Liability and the ACOG Quality and Patient Safety Committee and the AUGS Quality Committee. Ex. B, Woods Oct 5, 2015 Dep. at 19-24.

is clear that Dr. Woods is referring to his lack of regulatory and compliance expertise necessary to draft an IFU. Dr. Woods readily admitted that he is not an expert regarding "what risk information a medical device company needs to put inside an IFU," because the FDA has very specific guidelines that he is not prepared to address. Ex. B, Woods Oct. 5, 2015 Dep. at 93:12-24. It is within that context that Dr. Woods testified that he would not personally "call myself an expert" on warnings. *Id*.⁵

Plaintiffs do nothing but establish Dr. Woods's lack of qualification to opine regarding FDA regulations as applied to the development of product warnings – an opinion that he has not offered. Once again, under Plaintiffs' reasoning, Plaintiffs' own pelvic surgeon experts, such as Drs. Blaivas, Shull, Margolis, Elliott, and Rosenzweig, are not qualified to testify about product warnings in any form or fashion. If the Court allows Plaintiffs to elicit warnings opinions from their clinician experts, then fairness dictates that Defendants be allowed to elicit such opinions from Defendants' experts.

Dr. Woods is qualified to opine regarding the completeness and accuracy of the warnings from a clinical perspective. Dr. Woods's report and deposition testimony detail his extensive experience with the TVT and TVT-O devices, including particular risks and complications he has experienced and researched. Expert Report at 5. His extensive clinical experience with the product in issue is supplemented by an incredibly thorough review of the relevant literature and education he has provided to others. *Id.*, *passim*; Ex. C, Reliance List.

Dr. Woods will not testify about Ethicon's internal process for developing the TVT or TVT-O IFU warnings, nor will be opine on the applicable regulatory requirements or process.

⁵ Even if Dr. Woods made the broad admission that Plaintiffs suggest, as this Court has previously recognized, such characterization is not determinative on this Court. *See Huskey*, 29 F.Supp.3d at 734–35 (finding Dr. Johnson qualified to opine about polypropylene notwithstanding his deposition testimony "Q: Okay. You're not a biomaterials expert, are you? A: Um, I'm a clinical medical expert.").

Rather, Dr. Woods merely intends to opine on the adequacy and accuracy of the IFU warnings from a clinical perspective. Expert Report at 14, 84-85. He will opine regarding the risks associated with the devices, and whether the IFUs adequately conveyed these risks to physicians. *Id.*

Ethicon recognizes that this Court has previously precluded defense experts in these cases from opining that a "warning was adequate merely because it included the risks he has observed in his own practice." *Trevino*, 2016 WL 1718836 at *45. Plaintiffs do not challenge Dr. Woods's warning opinions on those grounds. Even if they did, such a challenge would lack merit. Although the Court has been clear that just because an expert had not seen a particular risk in his practice did not justify his testimony that the risk did not exist, *id.*, that is not what Dr. Woods seeks to do here. Instead, Dr. Woods will testify that the complications that Plaintiffs allege should have been in the IFUs: (a) are risks that a pelvic surgeon would already know, and therefore, need not be warned about; (b) are not genuine complications; or (c) are not attributable to the device.

As it relates to the latter two categories, Dr. Woods's report and deposition show that his opinions are based on his extensive clinical experience, *as well as* his thorough critique of scientific literature. *See, e.g.,* Expert Report at 23-25, 28, 59-60 (explaining why he disputes that mesh causes various conditions, such as damage from particle loss or contraction, cytotoxicity, or degradation). Thus, this is sufficient to distinguish the circumstances here from *Trevino. See Huskey*, 29 F. Supp. 3d at 734-35 (allowing Dr. Johnson to testify about evidence of absence because his opinions were also based on medical literature); *Carlson*, 2015 WL 1931311 at *12.6

⁶ While this Court has observed that "[a]bsence of evidence is not evidence of absence" *Tyree*, 54 F. Supp. 3d at 583-84, the observation only holds true where a cursory inquiry of the evidence has been made. For instance, if a physician is relying merely on his own experience to opine that a particular risk does not exist, the methodology may be flawed. However, where, as here, a physician examines the evidence outside of his own experience, such as

Moreover, Dr. Woods, as an experienced clinician, is well qualified to testify about complications that are "well-known and obvious to pelvic floor surgeons performing those types of procedures," such that they need not be included in an IFU. Expert Report at 84; *see also id.* at 27 ("All surgical procedures carry the risks of bleeding, infection, scar tissue formation, [and] damage to other organs"). The law imposes no duty to warn upon sophisticated users of products with respect to risks that the sophisticated users already know or should know. *See, e.g.*, Restatement (Third) of Torts: Product Liability §2 cmt. j (1998); Restatement (Second) of the Law of Torts §402A cmt. j; American Law of Product Liability 3d §32:69 (2016); *Willis v. Raymark Indus., Inc.*, 905 F.2d 793, 797 (4th Cir. 1990). In fact, 21 CFR § 801.109(c) states there is no duty to warn if "the article is a device for which the hazards, warnings and other information are commonly known to practitioners licensed by law to use the device."

This is an objective test not dependent on the knowledge of the individual surgeon, and Dr. Woods is certainly competent to share his opinions about what risks should be obvious to surgeons who use the devices and how an average clinician would construe the IFUs. Indeed, Ethicon writes its IFUs for pelvic floor surgeons like Dr. Woods. Under the learned intermediary doctrine, such surgeons are the ones who must be adequately warned. If Plaintiffs intend to argue at trial that Ethicon's IFUs failed to disclose certain risks, then it is only fair that Ethicon be allowed to defend itself by demonstrating that those risks were obvious to the users of the product (pelvic surgeons and urologists), and therefore, did not need to be included in the IFUs in accordance with the aforementioned law.

by critiquing the medical literature and studying the conclusions of medical organizations, then the physician's opinions have a reliable basis. If there is no reliable evidence of risk as determined by a detailed review of appropriate sources, there is no obligation to include the risk in the IFU warnings.

CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court deny Plaintiffs' motion to exclude the testimony of Dr. Woods.

Respectfully Submitted,

/s/ Christy D. Jones

Christy D. Jones
Butler Snow LLP
1020 Highland Colony Parkway
Suite 1400 (39157)
P.O. Box 6010
Ridgeland, MS 39158-6010
(601) 985-4523
Christy.jones@butlersnow.com

/s/ David B. Thomas

David B. Thomas (W. Va. Bar #3731) Thomas Combs & Spann PLLC 300 Summers Street Suite 1380 (25301) P.O. Box 3824 Charleston, WV 25338 (304) 414-1807 dthomas@tcspllc.com

COUNSEL FOR DEFENDANTS ETHICON, INC. AND JOHNSON & JOHNSON

IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION

Master File No. 2:12-MD-02327 MDL No. 2327

THIS DOCUMENT RELATES TO ETHICON WAVE 1 CASES

JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

CERTIFICATE OF SERVICE

I, Christy D. Jones, certify that on this date, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ Christy D. Jones

Christy D. Jones
Butler Snow LLP
1020 Highland Colony Parkway
Suite 1400 (39157)
P.O. Box 6010
Ridgeland, MS 39158-6010
(601) 985-4523
christy.jones@butlersnow.com

31038584v1